WAC 458-20-18801 Prescription drugs, prosthetic and orthotic devices, ostomic items, and medically prescribed oxygen Drugs prescribed for human use, medically prescribed oxygen, prosthetic devices, and durable medical equipment. (1) Definitions. As used in this section:

- (a) "Prescription drugs" are medicines, drugs, prescription lenses, or other substances, other than food for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other ailment in humans ordered by (i) the written prescription to a pharmacist by a practitioner authorized by the laws of this state or laws of another jurisdiction to issue prescriptions, or (ii) an oral prescription of such practitioner which is reduced promptly to writing and filled by a duly licensed pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is promptly reduced to writing and filled by the pharmacist, or (iv) physicians or optometrists by way of written directions and specifications for the preparation, grinding, and fabrication of lenses intended to aid or correct visual defects or anomalies of humans.
- (b) "Prescription" means a formula or recipe or an order written by a medical practitioner for the composition, preparation and use of a healing, curative or diagnostic substance, and also includes written directions and specifications by physicians or optometrists for the preparation, grinding, and fabrication of lenses intended to aid or correct visual defects or anomalies of humans.
- (c) "Other substances" means products such as catalytics, hormones, vitamins, and steroids, but the term generally does not include devices, instruments, equipment, and similar articles. However, "other substances" does include the needles, tubing, and the bag which are part of an intravenous set for delivery of prescription drugs. It also includes infusion pumps and catheters when used to deliver prescription drugs to a specific patient. These items are not conceptually distinct from the prescription drug solution. This same rationale applies to tubing and needles which are used in placing prescribed nutritional products in the patient's system. The stand which holds the intravenous set is not included nor are plain glass slides, plain specimen collection devices, and similar items which are used in the laboratory. This term does include diagnostic substances and reagents, including prepared slides, tubes and collection specimens devices which contain diagnostic substances and reagents at the time of purchase by a laboratory.

- (d) "Medical practitioner" means a person within the scope of RCW18.64.011(9) who is authorized to prescribe drugs, but excluding veterinarians, and for the purposes of this rule includes also persons licensed by chapter 18.53 RCW to issue prescriptions for lenses.
- (e) "Licensed dispensary" means a drug store, pharmacy, or dispensary licensed by chapter 18.64 RCW or a dispensing optician licensed by chapter 18.34 RCW.
- (f) "Prosthetic devices" are artificial substitutes which generally replace missing parts of the human body, such as a limb, bone, joint, eye, tooth, or other organ or part thereof, and materials which become ingredients or components of prostheses.
- (g) "Orthotic devices" are apparatus designed to activate or supplement a weakened or atrophied limb or function. They include braces, collars, casts, splints, and other similar apparatus as well as parts thereof. Orthotic devices do not include durable medical equipment such as wheelchairs, crutches, walkers, and canes nor consumable supplies such as embolism stockings, arch pads, belts, supports, bandages, and the like, whether prescribed or not.
- (h) "Ostomic items" are medical supplies used by colostomy, ileostomy, and urostomy patients. These include bags, tapes, tubes, adhesives, deodorants, soaps, jellies, creams, germicides, and sundry related supplies.
- (i) "Medically prescribed oxygen" means oxygen prescribed for the use in the treatment of a medical condition. For periods after July 27, 1991, this term shall include, but is not limited to, the sale or rental of oxygen concentrator systems, oxygen enricher systems, liquid oxygen systems, and gaseous, bottled oxygen systems for use by an individual under a prescription. (See RCW 82.08.0283.)
- (j) "Legend drugs" are those drugs which may not be legally dispensed without a prescription. These drugs are listed in the official United States pharmacopeia or similar source. (See RCW 69.41.010(8).) WAC 246 865 010(5) requires legend drugs to have a label stating that federal law prohibits dispensing without a prescription. Also refer to RCW 69.41.010(9).
- (k) "Nutrition products" are prescribed dietary substances formulated to provide balanced nutrition as a sole source of nourishment.
- (2) Business and occupation tax. The business and occupation tax applies to the gross proceeds from sales of drugs, medicines, prescription lenses, or other substances used for diagnosis, cure, mitigation, treatment, or prevention of disease or other

ailments in humans. Sales of these items to persons for resale are taxable under the wholesaling classification. Sales to consumers are taxable under the retailing classification. Persons who provide medical services to patients are taxable under the service and other business activities classification on the gross charge to the patient, notwithstanding that some prescription drugs may be separately charged to the patient. Persons who provide medical services should refer to WAC 458-20-151 and 458-20-168 for additional tax reporting information.

- (3) **Deductions**. The following may be deducted from gross proceeds for computing business and occupation tax:
- (a) Sales of prescription drugs and other medical and healing supplies furnished as an integral part of services rendered by a publicly operated or nonprofit hospital, nonprofit kidney dialysis facility, nursing home, or home for unwed mothers operated as a religious or charitable organization which meets all the conditions for exemption for services generally under RCW 82.04.4288 or 82.04.4289 (see WAC 458-20-168).
- (4) Retail sales tax. The retail sales tax applies upon all retail sales of tangible personal property unless expressly exempted by law.
- (5) **Exemptions**. The following exemptions apply from the retail sales tax and use tax.
- (a) Legend drugs are exempt from retail sales tax or use tax when sold for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other ailments of humans. This exemption applies to all levels of sales and distribution of legend drugs, including legend drugs given away as samples. Legend drugs are exempt from sales tax when sold to hospitals, doctors, dentists, or any other medical practitioner, as well as to patients. Sellers of legend drugs are not required to retain a resale certificate or other exemption documentation from the legend drug purchaser. The exemption applies at the time of purchase even if the hospital or medical practitioner who makes such purchases will not resell the legend drug as a separate line item charge to its patient.
- (b) The retail sales tax does not apply to sales of nonlegend drugs, nutrition products including dietary supplements or dietary adjuncts, medicines, prescription lenses, or other substances, but only when
- (i) Dispensed by a licensed dispensary
- (ii) Pursuant to a written prescription
 - (iii) Issued by a medical practitioner
- (iv) For diagnosis, cure, mitigation, treatment, or prevention of disease or other ailment in humans. (See RCW

82.08.0281.)

- (c) Laboratory reagents and other diagnostic substances are exempt from retail sales tax when used as part of a test prescribed to diagnose disease in humans. These items include, among others, reagents, calibrators, chemicals, gases, vacutainers with heparin or other chemicals or medicines, and prepared media. Control reagents are exempt, but only when the control reagents are used in performing tests prescribed for a patient. Reagents which are used to merely calibrate equipment and are not related to a test prescribed for a specific patient are not exempt.
- (d) The retail sales tax exemption applies also to intravenous sets, including the needles and tubing, when used for the administration of drugs prescribed to a patient. This also includes catheters, infusion pumps, syringes, and similar items when used for the delivery of prescription drugs. Medical gas delivery system components, including tubes, nebulizers, ventilators, masks, cannulae and similar items, are not conceptually distinct from the prescribed gases they deliver and are exempt from retail sales or use tax. The medical delivery system includes airway devices (tubes) which are prescribed to keep a patient's airways open and to deliver medical gases.
- (e) The retail sales tax does not apply to sales of prosthetic devices, orthotic devices prescribed by physicians, osteopaths, or chiropractors, nor to sales of ostomic items. (See RCW 82.08.0283.) Sutures, pacemakers, hearing aids, and kidney dialysis machines are examples of prosthetic devices. Drainage devices which are particularly prescribed for use on or in a specific patient are exempt from sales or use taxes as prostheses because they either replace missing body parts or assist dysfunctional ones, either on a temporary or permanent basis. A prosthetic device can include a device that is implanted for cosmetic reasons. Hearing aids are also exempt when dispensed or fitted by a person licensed under chapter 18.35 RCW. A heart lung machine used by a hospital in its surgical department is not an exempt prosthetic device.
- (f) The sale of medically prescribed oxygen is not subject to retail sales or use tax when sold to an individual having a prescription issued by a person licensed under chapter 18.57 or 18.71 RCW for use in the medical treatment of that individual.
- (g) The retail sales tax does not apply to the purchase of anesthesia gases, medical gases, contrast media, or irrigation solutions when these items are used under a physician's order as part of a medical treatment for a specific patient.
- (6) Proof of exemption. Persons selling legend drugs need

only to substantiate that the drugs meet the definition of legend drugs and are for use in the diagnosis, cure, mitigation, treatment, prevention of disease or other ailments in humans. Resale certificates or other exemption certificates are not required for these sales. For sales to consumers of nonlegend drugs, sellers must retain in their files the written prescription bearing the signature of the medical practitioner who issued the prescription and the name of the patient for whom prescribed. See also WAC 458 20 150 Optometrists, ophthalmologists, and oculists; 458-20-151 Dentists, dental laboratories and physicians; and 458 20 168 Hospitals. (a) Hospitals and physicians who purchase drugs for use in providing medical services to patients may purchase the drugs without payment of retail sales tax if the drugs will only be dispensed under a physician's order. It is not required that the hospital or physician make a specific charge to the patient for drugs dispensed under a physician's order for the drug purchase to be exempt from retail sales or use tax. This also includes the purchases of intravenous sets, catheters, infusion pumps, syringes, and similar items which will be used for delivery of prescription drugs. The hospital or physician may give the nonlegend drug supplier an exemption certificate. The certificate should be retained by the seller for a period of five years after the last sale covered by the certificate. Certificates should not be sent to the department of revenue. The certificate should be in the following form: Top of Form

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Prescription drug exemption

(name of vendor) will be prescribed and used for the treatment of illness or ailments of human beings. I shall maintain invoices and prescriptions or such other records as are necessary to account for the disposition of the drugs or other substances for which I have not paid retail sales tax. In the event that any such drug or substance is used without a prescription being issued, it understood that I am required to report and pay use tax measured by its purchase price. If I have indicated that this is a blanket certificate, this certificate shall be considered part of each order which I may hereafter give to vou, unless otherwise specified, and shall be valid for a period of four years or until revoked by me in writing. Description of drugs and other substances to be purchased: Single Purchase Blanket Certificate (indicate by check mark if certificate is for a single purchase or continuing purchases) (signature of purchaser or authorized agent) (title) (Revenue registration number of

buyer)

- (b) A blanket exemption certificate may be given if there will be continuing purchases from a particular supplier. Blanket exemption certificates should be renewed at intervals not to exceed four years. The purchaser should indicate by an appropriate check mark on the certificate whether the certificate is being used for a single purchase or will be for continuing purchases. It is unnecessary to list each and every drug on the exemption certificate if all drugs purchased from a particular supplier are exempt.
- (7) **Use tax.** The use tax does not apply to the use of articles and products which are exempt from sales tax as specified herein. (See RCW 82.12.0277.) This includes legend drugs which are given away as samples.
- (8) Examples. The following examples identify a number of facts and then state a conclusion. These examples should be used only as a general guide. The tax status of each situation must be determined after a review of all of the facts and circumstances.
- (a) ABC Hospital purchases both legend and nonlegend drugs. These drugs are held in inventory and dispensed to patients only under the written order of the patient's physician. These drugs are not billed specifically to the patient, but the cost is recovered through a general floor charge to the patient. ABC Hospital may purchase these drugs without payment of sales or use tax.
- (b) ABC Hospital purchases reagents for use in its laboratory which are nonlegend drugs. Laboratory reagents are chemical compounds used to promote reactions in the laboratory to aid in determining disease pathology and are not administered directly to the patient. These reagents are used for three purposes consisting of tests on the tissue from a specific patient, a control reagent which is not applied to the tissue from the patient but is used to measure or control the reaction, and a reagent used to calibrate equipment. The reagents used for the first two purposes may be purchased without payment of sales or use tax. The reagents for the calibration of equipment are also exempt if the equipment is calibrated as part of tests for a specific patient. Reagents used to calibrate equipment that is not part of a prescribed test for a patient are taxable.
- (c) XY Blood Bank purchases reagents which are nonlegend drugs. These reagents are used in determining the blood type and presence of disease. The blood is sold to local hospitals. The purchase of these reagents is taxable since they are not used to

provide treatment for a specific patient. Introduction. This rule provides general tax-reporting information for persons making sales of medical supplies, devices, or substances, and persons who manufacture medical supplies or devices. It also provides information about the retail sales and use tax exemptions, and the sale and use of certain medical substances, devices, and supplies for humans. In 2003, the Legislature adopted the medical definitions set forth in the national Streamlined Sales and Use Tax Agreement. The 2003 amendments to these statutes changed how sales of medical substances, devices, and supplies are taxed on and after July 1, 2004.

- (a) Additional rules. The department has adopted other rules addressing the taxability of various activities related to the providing of health care. Readers may also find helpful information in the following rules:
- (i) WAC 458-20-150(Optometrists, ophthalmologists, and opticians).
- (ii) WAC 458-20-151 (Dentists and other health care providers, dental laboratories and dental technicians).
- (iii) WAC 458-20-168 (Hospitals, medical care facilities, and adult family homes).
- (b) **Specific exemptions**. The medical exemptions discussed in this rule appear in the following subsections:
 - (i) Subsection (4) Drugs for human use.
 - (ii) Subsection (5) Over-the-counter drugs.
- (iii) Subsection (6) Laboratory reagents and other diagnostic substances.
- (iv) Subsection (7) Controls, calibrators, and standards used with laboratory test equipment.
 - (v)Subsection (8) Medically prescribed oxygen.
 - (vi) Subsection (9) Prosthetic devices.
 - (vii) Subsection (10) Kits and trays.
 - (viii) Subsection (11) Family planning items.
- (ix) Subsection (12) Human blood, tissue, organs, or body parts.
- (2) **General tax information.** This subsection provides general tax-reporting information for persons making sales of medical supplies, devices, or substances, and persons who manufacture medical supplies or devices.
- (a) Sales of medical substances, devices, and supplies.

 Sales of medical substances, devices, or supplies to consumers such as doctors, hospitals, or patients are subject to the retailing B&O and retail sales taxes, unless a specific exemption applies. Sales to persons who resell the items (e.g., pharmacies) are subject to the wholesaling B&O tax. Persons

making wholesale sales should refer to WAC 458-20-102 for information regarding their responsibility to obtain a resale certificates.

- (b) **Use tax**. Purchases of medical substances, devices, or supplies for purposes other than the diagnosis, cure, mitigation, treatment or prevention of disease in humans are purchases at retail and are subject to retail sales tax. If the seller does not collect retail sales tax, the purchaser must remit retail sales tax (commonly referred to as "deferred sales tax") or use tax on the amount paid for such medical supplies or devices directly to department unless they are otherwise exempt under the law. See WAC 458-20-178 (Use tax) for additional information on use tax.
- (c) Exemption certificates. Unless otherwise provided in this rule, sellers making sales to medical practitioners, nursing homes, and hospitals, must obtain an exemption certificate to document tax-exempt sales of the products discussed in this rule. The appropriate certificate in each case is a "Buyers' Retail Sales Tax Exemption Certificate." The certificate must be completed in its entirety, with the "Prescription items" box checked. The Buyer's Retail Sales Tax Exemption Certificate may be obtained by:
- (i) Using the department's Internet website at http://dor.wa.gov/;
- (ii) Using Fast Fax, part of the department's automated telephone system that allows a caller to directly receive the form by fax. This service may be accessed through the appropriate menu options at 1-800-647-7706;
- (iii) Calling the department's telephone information center at 1-800-647-7706;
- (iv) Requesting the form at any of the department's local field offices; or
 - (v) By mailing your request to:

Taxpayer Services

Department of Revenue

P.O. Box 47478

Olympia, WA 98504-7478.

- (d) Sales to a free hospital. RCW 82.08.02795 and RCW 82.12.02745 provide a retail sales and use tax exemption for sales to a "free hospital." See WAC 458-20-168 (Hospitals, medical care facilities, and adult family homes) for additional information about this exemption.
- (3) Manufacturing of medical supplies or devices. (a)
 Persons who manufacture products, including medical supplies or devices, in this state are subject to the manufacturing B&O tax

upon the value of the products. Manufacturers selling the products at retail or wholesale in this state are also subject to either the retailing or wholesaling B&O tax, as the case may be. In such cases, the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) classifications of the B&O tax, and claim a Multiple Activities Tax Credit (MATC). See also WAC 458-20-19301 for a more detailed explanation of the MATC.

(b) Persons who manufacture molds or other products that they use in a manufacturing process are subject to tax under the Manufacturing B&O tax classification upon the value of the product manufactured. (See also WAC 458-20-112 and 458-20-134 regarding "value of products" and "commercial or industrial use", respectively).

These persons also incur a use tax liability with respect to their use of the molds or products, unless a specific exemption applies. For example, RCW 82.12.02565 provides a use tax exemption for the use of certain molds in a manufacturing operation.(Refer to WAC 458-20-13601 for additional information regarding the manufacturing machinery and equipment exemption.)

- (4) Drugs for human use. RCW 82.08.0281 and RCW 82.12.0275 provide retail sales and use tax exemptions for drugs for human use dispensed or to be dispensed to patients, pursuant to a prescription. There are also sales and use tax exemptions for disposable devices used to deliver drugs for human use, pursuant to a prescription under RCW 82.08.XXX1 and RCW 82.12.XXX1.

 [Drafter's note the references to RCW 82.08.XXX1 and 82.12.XXX1 refer to sections 404 and 407, chapter 168, Laws of 2003. These new sections were added by SB 5783 and have yet to be codified.]

 Sales of drugs or disposable devices used to deliver drugs for human use to medical practitioners, nursing homes, and hospitals, are exempt only if a properly completed exemption certificate is obtained to support the exempt nature of the sale. See subsection (2)(c) of this rule for information about exemption certificates.
- (a) What is a prescription? A "prescription" is an order, formula, or recipe issued in any form of oral, written, electronic, or other means of transmission by a duly licensed practitioner authorized by the laws of this state.
- (b) What is a drug? A "drug" is a compound, substance, or preparation, and any component of a compound, substance, or preparation, other than food and food ingredients, dietary supplements, or alcoholic beverages:

- (i) Recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; or
- (ii) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
- (iii) Intended to affect the structure or any function of the body.

[Drafter's note - Under current law a prescription is not needed to purchase insulin exempt from retail sales tax. Under chapter 168, Laws of 2003, a prescription is needed. The Department anticipates a correction bill being run during the 2004 session.]

- (c) What are disposable devices used to deliver drugs?

 "Disposable devices used to deliver drugs" are single use items such as syringes, tubing, or catheters used to deliver drugs for human use dispensed to patients pursuant to a prescription. The stand that holds the tubing or catheter is not a disposable device used to deliver drugs.
- (d) **Example**. The example in this subsection identifies a number of facts and then states a conclusion. This example should only be used as a general guide. Similar determinations for other situations can be made only after a review of all facts and circumstances.

Nursing Home purchases single use syringes, tubing used to deliver drugs, and stands used to hold the intravenous (IV) fluid containers. Retail sales tax does not apply to the purchase of single use syringes and tubing, providing Nursing Home gives the seller a completed "Buyers' Retail Sales Tax Exemption Certificate." Retail sales tax does apply to the IV stands because the stands are "durable medical equipment." For information about durable medical equipment, see subsection (13), below.

- (5) Over-the-counter drugs. RCW 82.08.XXX2 and RCW 82.12.XXX2 provides a sales and use tax exemption for "over-the-counter drugs" for human use dispensed or to be dispensed to patients pursuant to a prescription. [Drafter's note the references to RCW 82.08.XXX2 and 82.12.XXX2 refer to sections 405 and 408, chapter 168, Laws of 2003. These new sections were added by SB 5783 and have yet to be codified.]
- (a) What are over-the-counter drugs? An "over-the-counter drug" is a drug that contains a label identifying the product as a drug as required by 21 Code of Federal Regulations (CFR) Sec. 201.66, as amended or renumbered on January 1, 2003. The label includes a:
 - (i) "Drug facts" panel; or

- (ii) Statement of the "active ingredient(s)" with a list of those ingredients contained in the compound, substance, or preparation.
- (b) **Examples**. The examples in this subsection identify a number of facts and then state a conclusion. These examples should only be used as a general guide. Similar determinations for other situations can be made only after a review of all facts and circumstances.
- (i) Patient's medical practitioner prescribes over-the-counter pain relief medication. Patient takes the prescription to the pharmacy. The sale of the over-the-counter drug is exempt from retail sales tax. If the Patient's medical practitioner recommends to Patient an over-the-counter pain relief medication, without completing a prescription for the medication, the sale of the over-the-counter medication is subject to sales tax.
- (ii) Hospital makes bulk purchase of various over-the-counter drugs to dispense to patients pursuant to a doctor's prescription. Hospital's purchases of such drugs are exempt from sales tax providing Hospital gives seller a "Buyers' Retail Sales Tax Exemption Certificate" as discussed above in subsection (2)(c).
- (6) Laboratory reagents and other diagnostic substances. The definition of drug includes compounds, substances, or preparations (e.g., laboratory reagents and other diagnostic substances) used for the diagnosis of disease. Thus, sales of laboratory reagents and other diagnostic substances are not subject to retail sales tax when used as a part of a test prescribed by a medical practitioner to diagnose disease in humans. RCW 82.08.0281. RCW 82.12.0275 provides a comparable use tax exemption. Persons making tax-exempt sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale (see subsection (2)(c), above).
- (a) What are laboratory reagents and other diagnostic substances? "Laboratory reagents and other diagnostic substances" are substances employed to produce a chemical reaction in order to detect, measure, or produce, other substances. To be a diagnostic substance, the application of the substance to a patient's specimen must result in the identification of the characteristics of a particular disease. The function of the substance determines its taxability.
- (b) Examples of laboratory reagents and other diagnostic substances. This subsection (b) provides examples of laboratory reagents and other diagnostic substances that may qualify for a sales or use tax exemption under RCW 82.08.0281 and 82.12.0275,

provided all requirements for the exemption are met. The
following items are reagents or other diagnostic substances:

- (i) Stains, dyes, and decolorizers that react with and cause a change in a cellular tissue. The substances are often used to stain the cell tissues in a manner that will mark or highlight certain portions of cells;
- (ii) Fixatives, decalcifying solution, dehydrating solution, and clearing agents that chemically react with the patient's specimen;
- (iii) Test strips impregnated with a reagent, which when, applied to a patient's specimen, test for indicators of a disease; and
- (iv) Test tubes or cylinders containing reagents or medicines, and prepared media. The term "prepared media" includes transport media if the resulting culture grown on the medium are used in performing diagnostic tests for specific patients.
- (c) Items that are not reagents. Some substances are used solely for purposes of preparing specimens for examination and diagnosis or to facilitate examination of a specimen. Such substances do not themselves produce a chemical reaction resulting in the detection, measurement, or production of another substance. They merely facilitate or enable specimen testing and are not exempt under RCW 82.08.0281 or 82.12.0275. The following items are not reagents:
- (i) Paraffin that is extracted from a tissue specimen without having chemically altered the cells;
- (ii) Gelatin that is extracted out of the specimen before staining and leaves the cell structures unaffected;
 - (iii) Electrodes;
 - (iv) Tissue cassettes;
 - (v) Freezing medium;
 - (vi) Liquid agar when used to gel patient specimens;
- (vii) Test tubes or cylinders that do not contain a reagent; (viii) Plain slides and cover slips that are not coated with a reagent;
- (ix) Mounting medium to adhere the cover slip to the slide; and
- (x) Acids and other solutions when used for cleaning purposes.
- (d) Multiple use substances. Some reagents or other diagnostic substances have multiple uses, some of which do not qualify for a sales or use tax exemption. Such substances are exempt only to the extent they are used as part of a test prescribed to diagnose disease in humans. For example, alcohol

can be used either as a reagent (e.g. to react with a cellular tissue) or to clean counters, furniture etc. Alcohol, if used as a cleaning agent, is subject to retail sales tax.

- (7) Controls, calibrators, and standards used with laboratory test equipment. The sales and use tax exemption provided by RCW 82.08.0281 and 82.12.0275 apply under certain conditions to compounds, substances, or preparations used in conjunction with the test of patient specimens in a medical laboratory. Persons making tax-exempt retail sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale (see subsection (2)(c), above).
- (a) What are controls, and when are they exempt from retail sales or use tax? A "control" is a material, solution, lyophilized (freeze-dried) preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the substances of interest in the control are known within limits determined during its preparation or before routine use. Controls are generally used with each test of patient specimens to validate the accuracy of that particular test.

Controls are not subject to sales or use tax when used in laboratory equipment as part of a test prescribed by a medical practitioner for diagnosis of disease in humans.

(b) What are calibrators, and when are they exempt from retail sales or use tax? A "calibrator" is a material, solution, or lyophilized (freeze-dried) preparation designed to be used in calibration of medical laboratory machines. The values or concentrations of substances of interest in the calibration material are known within limits determined during its preparation or before use. Calibrators are generally used at specified intervals such as every eight hours, at midnight, or at shift changes, in accordance with the machine manufacturer's requirements or the requirements of administering agencies to verify the accuracy of the machine.

Reagents used to calibrate equipment are exempt from sales or use tax if the equipment is calibrated as part of a test for a specific patient. Reagents used to calibrate equipment that is not part of a prescribed test for a patient are subject to retail sales tax.

(c) What are standards, and when are they exempt from retail sales or use tax? A "standard" is a reference material of fixed and known chemical composition capable of being prepared in an essentially pure form. "Standard" also includes any certified reference material generally accepted or officially recognized as the unique standard used to test and calibrate medical lab

equipment. Standards are often used in the original setup of medical lab equipment.

Because a standard is used to test and calibrate equipment, standards are subject to retail sales tax.

- (8) Medically prescribed oxygen. RCW 82.08.0283 provides a retail sales tax exemption for sales of medically prescribed oxygen and its delivery systems for single patient use prescribed by persons licensed under chapter 18.57 RCW or 18.71 RCW. RCW 82.12.0277 provides a complementary use tax exemption. Persons making tax-exempt sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale (see subsection (2)(c), above).
- (a) What is medically prescribed oxygen? "Medically prescribed oxygen" is oxygen prescribed for use in the treatment of a medical condition in a human. This term includes, but is not limited to, the sale or rental of oxygen concentrator systems, oxygen enricher systems, and liquid or gaseous bottled oxygen systems.
- (b) What does a delivery system for medically prescribed oxygen (i.e., an oxygen delivery system") include? An "oxygen delivery system" includes a regulator, tubing, cannula, and mask as well as the oxygen generation or storage device. An oxygen delivery system does not include a separate cart used to transport the delivery system. The cart is durable medical equipment. For information about durable medical equipment, see subsection (13), below.

[Drafter's note - Under current practice a nebulizer is considered a medical gas delivery system and is exempt from retail sales tax. Under chapter 168, Laws of 2003, a nebulizer is durable medical equipment and as such is taxable. The Department anticipates a correction bill being run during the 2004 session.]

[9] Prosthetic devices. RCW 82.08.0283 provides a retail sales tax exemption for sales of prosthetic devices prescribed for an individual by a person licensed under chapter 18.22, 18.25, 18.57, or 18.71 RCW. [Drafter's note - The list of those who can prescribe prosthetics should include audiologists under chapter 18.35 RCW, optometrists under chapter 18.53 RCW, and dentists under chapter 18.32 RCW. The Department anticipates a correction bill being run during the 2004 session.] The exemption includes repair and replacement parts, as well as labor and services rendered in respect to repairing, cleaning, altering, or improving prosthetic devices. RCW 82.12.0277 provides a corresponding use tax exemption. Persons making taxexempt sales of these items to medical practitioners, nursing homes, and hospitals, must obtain an exemption certificate to

substantiate the exempt nature of any sale (see subsection
(2)(c), above).

- (a) What is a prosthetic device? A "prosthetic device" is a replacement, corrective, or supportive device, including repair and replacement parts for a prosthetic device, worn on or in the body to:
- (i) Artificially replace a missing portion of the body;
 (ii) Prevent or correct a physical deformity or malfunction;
 or
 - (iii) Support a weak or deformed portion of the body.
- _(b) **Examples of prosthetic devices.** Prosthetic devices include but are not limited to the following:
- (i) Ostomic items for colostomy, ileostomy, or urostomy patients. "Ostomic items" are medical supplies used by colostomy, ileostomy, and urostomy patients and include bags, belts to hold up bags, tapes, tubes, adhesives, deodorants, soaps, jellies, creams, germicides, and related supplies.

 "Ostomic items" does not include undergarments, pads and shields to protect undergarments, sponges, or rubber sheets; [Drafter's note Under current law a prescription is not needed to purchase ostomic items exempt from retail sales tax. Under chapter 168, Laws of 2003, a prescription is needed. The Department anticipates a correction bill being run during the 2004 session.]
 - (ii) Eye glass frames and lenses and contact lenses;
- (iii) Dental prostheses, including but not limited to full and partial dentures, crowns, inlays, fillings, braces, and retainers;
 - (iv) Hearing instruments;
- (v) Drainage and suction devices for single patient use because they serve the same drainage functions as the body's natural systems;
- (vi) Sutures, staples, and skin glue for closing wounds along with disposable needles or staplers used to apply them.

 Reusable needles or staplers are durable medical devices. For information about durable medical equipment, see subsection (13), below;
 - (vii) Implanted pacemakers; and
- (viii) Braces, collars, casts, splints, embolism stockings, arch pads, pelvic traction belts, traction pulley clamp assemblies and cords, supports, post-operation shoes, cast shoes, specialized orthotic shoes, and other similar apparatus.
- (10) **Kits or trays.** Medical procedure kits or trays are generally purchased from the vendor as a plastic-wrapped package that includes the various items needed to perform a particular medical procedure. The package often includes items that if

purchased separately are subject to retail sales tax as well as items that are exempt. This subsection explains how to determine whether a particular medical procedure kit or tray is exempt from sales or use tax. Persons making tax-exempt sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale (see subsection (2)(c), above).

- (a) Determining the taxability of kits. A two-part test is used to determine whether a particular medical procedure kit or tray is taxable or exempt. To be exempt from retail sales or use tax, the kit or tray must meet both of the following requirements:
- (i) It must be designed to support the use of a tax-exempt medical item in a procedure on a patient; and
 - (ii) It must include that tax-exempt medical item.
- (b) **Examples**. The examples in this subsection identify a number of facts and then state a conclusion. These examples should only be used as a general guide. Similar determinations for other situations can be made only after a review of all facts and circumstances.
- (i) A glucose testing kit includes a glucose meter, five sample test reagent strips, and lancets. While the five sample test reagent strips are tax-exempt as reagents, the kit is designed to support the use of the glucose meter, which is durable medical equipment. (Refer to subsection (13) of this rule for a discussion of the taxation of durable medical equipment.) The purchase of the glucose testing kit is subject to retail sales tax.
- (ii) An angioplasty kit contains an angioplasty catheter, masks, gloves, hats, and gowns for the surgical team, drapes, bowls, scalpels, clamps, syringe with lidocane, introducer needle, guidewire, dilators, and guiding catheter. This kit is designed to support the use of the angioplasty catheter, which is an exempt disposable device used to deliver drugs. The purchase of the angioplasty kit is not subject to retail sales tax.
- (11) Family planning items. Under certain conditions RCW 82.08.0281 and 82.12.0275 provide a sales and use tax exemption for family planning items.
- (a) What are family planning items? "Family planning items" include all single patient use items either ingested by or attached or applied to persons for the purpose of promoting, inhibiting, or determining conception.
- (b) **Conditions for exemption.** For the sales tax exemption to apply, one of the following conditions must be met:
- (i) The family planning item is supplied by a family planning clinic that is under contract with the Washington State

department of health to provide family planning services. Family planning clinics furnishing these items are not required to obtain or maintain files of prescriptions or exemption certificates to document the tax-exempt nature of these sales; or

- (ii) The family planning items are or will be dispensed to patients, pursuant to a prescription. Persons making tax-exempt sales of these items to medical practitioners, clinics, or hospitals, must obtain an exemption certificate to substantiate the exempt nature of any sale (see subsection (2)(c), above).
- (12) Human blood, tissue, organs, or body parts. RCW 82.08.02806 provides a retail sales tax exemption for human blood, tissue, organs, or body parts when used for medical research or quality control testing purposes. RCW 82.12.02748 provides a comparable use tax exemption. Persons making sales of these items are not required to obtain or maintain files of prescriptions or exemption certificates to support the tax-exempt nature of these sales.
- (a) What is human blood, tissue organs, or body parts? For the purposes of this exemption the following definitions from RCW 82.04.324 apply:
- (i) "Blood" means human whole blood, plasma, blood derivatives, and related products.
- (ii) "Tissue" includes human musculoskeletal tissue, musculoskeletal tissue derivatives, and related products.
- (iii) "Organs" or "body parts" means a part of a human body having a special function.
- (b) Materials consisting of both human and animal components. Materials consisting of both human and animal components are not "human blood, tissue, organs, or body parts" and do not qualify for this exemption.
- (13) Durable medical and mobility enhancing equipment.

 Retail sales or use tax applies to the sale or use of durable medical equipment and mobility enhancing equipment, unless a specific exemption applies.
- (a) What is durable medical equipment? "Durable medical equipment" is equipment, including repair and replacement parts for durable medical equipment, but does not include mobility enhancing equipment, that:
 - (i) Can withstand repeated use;
- (ii) Is primarily and customarily used to serve a medical purpose;
- (iii) Generally is not useful to a person in the absence of illness or injury; and
 - (iv) Does not work in or on the body.

- (b) What is mobility enhancing equipment? "Mobility enhancing equipment" is equipment, including repair and replacement parts for mobility enhancing equipment, but does not include medical equipment, that:
- (i) Is primarily and customarily used to provide or increase the ability to move from one place to another and that is appropriate for use either at home or in a motor vehicle;
- (ii) Is not generally used by persons with normal mobility; and
- (iii) Does not include any motor vehicle or equipment on a motor vehicle normally provided by a motor vehicle manufacturer.
- (c) Are kidney dialysis machines subject to retail sales
 tax? RCW 82.08.XXX3 provides a specific sales tax exemption for
 kidney dialysis machines and repair parts. The exemption does
 not, however, include charges for repair labor. RCW 82.12.XXX3
 provides a comparable use tax exemption. [Drafter's note the
 references to RCW 82.08.XXX3 and 82.12.XXX3 refer to sections 410
 and 411, chapter 168, Laws of 2003. These new sections were
 added by SB 5783 and have yet to be codified.]